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| APPLICATION NO.            | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|-------------|----------------------|---------------------|------------------|
| 10/045,688                 | 10/29/2001  | Marian L. Larson     | ML-01-US-DIV        | 1913             |
| 7590                       |             | 01/29/2004           | EXAMINER            |                  |
| Robert L. McDowell         |             | THANH, LOAN H        |                     |                  |
| 1170 Jackson Heights Drive |             | ART UNIT             |                     |                  |
| Webster, NY 14580          |             | PAPER NUMBER         |                     |                  |
|                            |             | 3763                 |                     |                  |
| DATE MAILED: 01/29/2004    |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N

10/045,688

Applicant(s)

LARSON ET AL.

Examiner

LoAn H. Thanh

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 9-11, 14 and 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-8, 12, 13 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other:

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of species III in Paper No. 7 is acknowledged. The traversal is on the ground(s) that claims 1, 6-13 are generic. This is not found persuasive because claims 9-11 are directed to a cross link alginate which belongs to species 1. However, The Examiner is in agreement that claims 1,6-8,12-13 are generic. With respect to the restriction requirement, it is the Examiner's position that a restriction is warranted by the present Examiner. A restriction can be made at any time during prosecution if deemed warranted.

Claims 2-4,9-11,17-20 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

The pending claims to be treated on the merits are 1,5-8,12-13,15.

The requirement is still deemed proper and is therefore made FINAL.

An action on the merits now follows.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 5- 8, and 12-13,15 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al.

Sahatjian et al. teach an implantable drug-deliverable device with a hydrogel coating or film, selected from a group of hydrogel polymer including polyethylene oxides. Sahatjian et al. teach a drug which is incorporated into the hydrogel polymer which is coated onto a stent/vascular graft. Sahatjian et al. further teach a coating such as a hydrogel polymer which is water soluble such as polyethylene glycol (carbowax) or polyethylene oxide or a biodegradable. In another interpretation, the hydrogel polymer is the water soluble polymer. It is considered that applicant is intending to claim a properties of a polymer such as biodegradable, bioabsorbable bioerodable. It is the Examiner's position that the prior discloses the same polymer of applicant lacking any further structural distinguishing features it is maintained that the prior art of record anticipates the claim of applicant. See abstract, col. 2, lines 10-25, col. 3, lines 57-63.

Claims 1, 5- 8, and 12-13,15 rejected under 35 U.S.C. 102(b) as being anticipated by Dayton ( U.S. Patent No. 5,449,382) .

Dayton discloses a device comprising a stent/vascular graft comprising a hydrogel polymer such as polyethylene, polyglycolic acid polymers, polylactic acid polymers ( specifically disclosed as biodegradable ), hydrogels and combinations, copolymers and blended mixtures thereof admix with a drug/ bioactive substance. Polyglycolic acid polymers and polylactic acid polymers are specifically disclosed as biodegradable.

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### ***Response to Arguments***

Applicant's arguments filed 03/24/03 have been fully considered but they are not persuasive. Applicant's arguments with respect to the properties of the hydrogel such as in vivo biodegradable, bioerodable or bioabsorbable is not persuasive. Examiner has cited specific references in the prior art which teaches the hydrogel to be one of those claimed properties. Further, lacking any structurally distinguishing features, the prior art still anticipates the claims since the prior art teaches the same polymer. One of ordinary skill in the art knows that properties of the polymer would be inherent properties.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is 703-305-0038. The examiner can normally be reached on Mon-Fri (alternate Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



LoAn H. Thanh  
Primary Examiner  
Art Unit 3763

LT